--97. (New) The monoclonal antibody according to claim 96, wherein the donor immunoglobulin is a murine immunoglobulin.--

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--98. (New) The monoclonal antibody according to claim 78, wherein the antibody is antibody PA8 (ATCC Accession No. HB-12605), antibody PA9 (ATCC Accession No. PA10 (ATCC Accession No. HB-12607), antibody P11(ATCC Accession No. HB-12608), or antibody PA12 (ATCC Accession No. 12609), or antibody PA14(ATCC Accession No.HB-12610).--

--99. (New) A hybridoma producing the monoclonal antibody according to claim 98.--

REMARKS

Claims 1-3, 5, 16, 20, 24, 26, 36, 46, 58-68, 70, 72, 74 and 76 are pending in the subject application. Applicants have herein canceled claims 1-3, 5, 16, 20, 24, 26, 36, 46, 58-68, 70, 72, 74 and 76 without disclaimer or prejudice to their right to pursue the subject matter of these claims in a later-filed application. Applicants have herein added new claims 78-99. Support for these claims may be found inter alia in the specification as follows: claim 78: page 17, lines 20-24; claim 79: page 17, lines 25-26; claim 80: page 17: lines 26-27; claim 81: page 17, lines 28-29; claim 82: page 17, line 37 to page 18, line 1; claim 83: page 18, lines 1-2; claim 84: page 17, lines 27-29; claim 85: page 17, lines 34-35; claim 86: page 17, lines 29-31; claim 87: page 17, lines 32-34; claim 88: page 22, lines 5-11; claim 89: page 22, lines 5-20; claim 90: page 22, lines 13-14; claim 91: page 23, lines 6-17;

claim 92: page 22, lines 19-24; claim 92: page 22, lines 28-29; claim 93: page 22, lines 19-24; claim 94: page 24, lines 4-10; claim 95: page 24, lines 6-8; claim 96: page 24, lines 15-17; claim 97: page 23, lines 32-37; claim 98: page 22, lines 5-11; claim 99: page 15, lines 5-6. This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested such that claims 78-99 will be pending.

Sequence

The Examiner stated that this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) and directed applicants attention to Figure 4. The Examiner stated that however, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

In response, applicants submit a paper copy of the Sequence Listing attached hereto as **Exhibit B** in compliance with the requirements of 37 C.F.R. §1.824. In addition applicants submit herewith a computer readable form (CFR) copy of the "Sequence Listing" as required by 37 C.F.R. §1.825(d). Further, applicants submit herewith as **Exhibit C** a statement in accordance with 37 C.F.R. §1.821(f), certifying that the substitute computer readable form containing the nucleic acid and/or amino acid sequences as required by 37 C.F.R. §1.821(e) contains the same information which was submitted as the "Sequence Listing" and contains no new matter.

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Restriction under 35 U.S.C. §121

The Examiner required restriction to one of the following inventions under 35 U.S.C. § 121:

I. Claims 1-3, 5, 16, 20, 24, 26, 36, 46, and 58-62, allegedly drawn to synergistic compositions for inhibiting HIV-1 infection, classified in Class 530, subclass 388.22;

II. Claim 63, allegedly drawn to a method of treating HIV-1 infection, classified in Class 424, subclass 144.1.

III. Claim 64, allegedly drawn to a method of preventing HIV-1 infection, classified in Class 424, subclass 144.1.

IV. Claim 65, allegedly drawn to monoclonal antibodies to the CCR-5 chemokine receptor, classified in Class 530, subclass 388.22.

V. Claims 66-67, allegedly drawn to humanized antibodies specific for the CCR-5 chemokine receptor, classified in Class 530, subclass 387.3.

VI. Claims 68, 70, 72, and 74, allegedly drawn to nucleic acids encoding the antibody a monoclonal antibody to CCR-5 chemokine receptor, classified in Class 536, subclass 23.53.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons; The Examiner

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stated that inventions (I and IV-VI) and (II-III) are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) The Examiner stated that the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). The Examiner stated that in the instant case the antibodies of the claimed invention produced by the nucleic acids of Group VI can be used to either treat an existing HIV infection or preventing HIV-1 infection as demonstrated by the methods of Groups II-III. The Examiner stated that further, the products of Groups I and IV-VI differ one from another in their physical properties such as chemical structure, primary sequence and molecular weight and are novel and unobvious in view of each other. The Examiner stated that therefore, the inventions of Groups I and IV-VI are patentably distinct. The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separated status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

The Examiner also stated that claim 65 is generic to a plurality of disclosed patentably distinct species comprising monoclonal antibodies specific for the CCR-5 chemokine receptor. The Examiner stated that these antibodies differ in their chemical, physical and immunological properties and are novel and unobvious in view of each other and are, therefore, patentably distinct.

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The Examiner stated that applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed. The Examiner stated that should applicant traverse on the ground that the species are not patentably distint, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. The Examiner stated that in either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

In response, applicants have herein canceled claims 1-3, 5, 16, 20, 24, 26, 36, 46, 58-68, 70, 72, 74 and 76 without disclaimer or prejudice and added new claims 78-99. Applicants respectfully request that the Examiner examine newly added claims 78-100 on the merits. In the event that the Examiner chooses the characterize newly added claims 78-99 as corresponding to Examiner's Groups IV and V, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group V, characterized by the Examiner as humanized antibodies specific for the CCR5 chemokine receptor, which are encompassed by newly added claims 78-97.

Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants contend that newly added claims 78-82 are not independent and do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." Newly added claims 78-99 relate to monoclonal antibodies that encompass humanized antibodies. A humanized antibody shares similar structure with a non-humanized antibody in that it maintains the same binding portion, i.e. the CDRs which binds to an epitope on the CCR5 receptor. Accordingly, the primary sequence in the CDR binding portion would not differ between the humanized and non-humanized forms. Accordingly, they share similar structural characteristics. In addition, they share similar functional characteristics in that they bind to an epitope of CCR5.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of

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prior art with regard to humanized versions of an antibody will reveal whether any prior art exists as to a non-humanized version of an antibody because they would share the same CDR binding domain. Since there is no burden on the Examiner to examine newly added claims 78-99 in the subject application, the Examiner must examine the entire application on the merits.

In response to the election of species requirement, Applicants would like to point out that claim 65 is a Markush-type claim. MPEP guidelines state that if members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits even though they are directed to independent and distinct inventions (MPEP 803.02). Applicants submit that unity of invention exists, as the antibodies included in the Markush group 1) share a common utility, ie. binding to CCR5, and 2) share a substantial structural feature essential to the utility, ie. comprise CDRs that bind to an epitope on CCR5. Applicants submit that in the case of claim 65, the election of species is improper, and ask the Examiner to reconsider the election of species requirement. New claims 88 and 89 recite a Markush grouping and claims are presented in the present amendment that are generic to claims 88 and 89 . However, to be responsive to the election of species requirement, Applicants elect the species of antibody, PA14 (ATCC Accession No. HB-12610) as it relates to a species of the Markush group of claims 88 and 89, and a species of the generic claims directed to monoclonal antibodies comprising CDRs that bind CCR5.

Applicants urge that if in the Examiner's search, no prior art

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is found that could impact the patentability of the elected species, the search of the Markush-type claim should be extended to the non-elected species (MPEP 803.02).

Applicant maintains that claims 78-99 define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner examine claims 78-99 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone either of them at the number provided below.

No fee, other than the enclosed $1096.00 fee, which includes the $200.00 fee for a two month extension of time and the $896.00 fee for additional claims, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White
Registration No. 28,678
Spencer H. Schneider
Registration No. 45,923
Attorneys for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

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